EXHIBIT 12

All Active CAPA's

Accountability Type	Site of Accountabiliy	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Corporate	CAPA				Redacted					
		CAPA080107	Jun 13, 2008	108 days	Implementation	Audit Observation	Corrective	Quality Systems	CAPA	Management of corrective action is not granting a solution in due time. See attachment for details.
		CAPA080137	Sep 4, 2008	24 days	Failure Investigation	Systemic Issue	Preventive	Quality Systems	Document Controls	Gaps have been identified in the Service and Repair area regarding the Service Bulletin process.
	CAPA	**3**								
	Global Supply Chain	CAPA060056	Mar 14, 2006	929 days	Implementation	Systemic Issue	Corrective	Product Process	Products, All: Conversion	The process for verifying the manual loading of changes to the Product Bill of Materials (BOM) into the JDE ERP system needs improvement. The scope is North America only.
		CAPA080147	Sep 20, 2008	9 days	Failure Investigation	Process Deviation	Corrective	Product Process	PDS Plus: Impregnation	During an investigation of code number D9956 related to triclosan levels, it was noticed that this code has not acceptable process validation to support its manufacture.
	Global Supply Chain	**2**								
	Information Management	CAPA080045	Mar 10, 2008	203 days	Implementation	Process Deviation	Corrective	Product Process	Products, All: Labeling	Issue with Thunderbird print drivers that is causing intermittent data integrity problems that manifest themselves in the form of corrupt print data when printing labels on sutures. The downtime created by this situation is unacceptable.
	Information Management	**1**								

Plaintiffs
EXHIBIT NO. 253
2/8/12
A. M. MITCHELL

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Corporate										
		Redacted								
	Operations Integrations	**1**								
	Operations Management	CAPA080018	Jan 29, 2008	243 days	Implementation	Predictive Indicator	Preventive	Quality Systems	Resources/ Personnel	The increased complexity of new products being introduced in the Neuchâtel facility requires that an organizational capability assessment be performed, and a plan to close potential skills and competencies gaps be developed and executed.
	Operations Management	**1**								
	Quality Operations									
		Redacted								
		CAPA080059	Mar 26, 2008	186 days	Failure Investigation	Process Deviation	Corrective	Quality Systems	Acceptance Status	The quarantine process is lacking with distribution centers, including affiliates. See attachment.
		CAPA080139	Sep 10, 2008	18 days	Requested	Audit Observation	Corrective	Quality Systems	CAPA	Investigation into Gynemesh confirmed complaint was not adequate as documented in CAPA070084. There is no documentation to show that units on quarantine in the distribution center and retention samples were evaluated.
	Quality Operations	**3**								
	Quality Systems and Compliance	CAPA060061	Mar 21, 2006	923 days	Implementation	Audit Observation	Corrective	Quality Systems	Resources/ Personnel	Although there are task specific procedures for training, the Franchise does not have a comprehensive training procedure

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
										or process.
Corporate	Quality Systems and Compliance	CAPA070011	Jan 16, 2007	621 days	Implementation	Audit Observation	Corrective	Quality Systems	Document Controls	Ethicon is not compliant to J&J Corporate records management requirements. Ethicon cannot appropriately provide all relevant documents in case of litigation or inspection.
		CAPA070082	Jun 21, 2007	465 days	Failure Investigation	Systemic Issue	Corrective	Quality Systems	Quality Records	Multiple Ethicon plants have created interplant quality agreements with no defined process.
		CAPA070121	Aug 22, 2007	403 days	Implementation	Negative Trend	Corrective	Quality Systems	CAPA	As a result of Management Review, this CAPA will investigate cycle time and due date adherence within the quality subsystems of NCR, Complaints, Internal Audits and CAPA and implement an improvement plan.
		CAPA080016	Jan 29, 2008	243 days	Implementation	Systemic Issue	Preventive	Quality Systems	Document Controls	Current change mgt & design control processes and systems are complex, non-integrated, and inefficient. There is also poor risk and impact assessment capability. This can lead to regulatory compliance issues and remote potential for patient risk.
		CAPA080077	May 2, 2008	149 days	Implementation	Audit Observation	Corrective	Quality Systems	Purchasing Controls	Procedure OP603-133 Revision 28 "Procedure for the Supplier Quality Audit Process" required supplier audit files were not accurate or complete.
		CAPA080103	Jun 12, 2008	109 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Document Controls	Change request process does not conform to documented requirements. Specifically the change request form CR-0015416

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Corporate	Quality Systems and Compliance									was not completely correct as required in the Ethicon Change Control System User Manual PR-0000001.
		CAPA080140	Sep 10, 2008	18 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Statistical Techniques	The process of how to track and trend quality data is not defined.
	Quality Systems and Compliance	**8**								
	Regulatory Affairs	CAPA070180	Dec 12, 2007	292 days	Implementation	Process Deviation	Corrective	Quality Systems	Advertising and Promotions	Evithrom promotional material incorporates statements/ graphics that the agency has deemed not appropriate.
		Redacted								
		Redacted								
		CAPA080113	Jun 19, 2008	102 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Document Controls	Legacy technical files in some cases remain deficient in reference to standards and some are deficient in critical areas such as Risk Management, Clinical Data, and Post Market Surveillance.
	Regulatory Affairs	**4**								
		Redacted								

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Corporate	Research and Development									combo (Drive connector) and Tri-Y manifold.
		CAPA070060	May 15, 2007	502 days	Effectivity	Product Complaint	Corrective	Product Family	MDU	Damage to coupler and/or connector of the Motor Drive Unit.
					Redacted					
		CAPA080138	Sep 8, 2008	21 days	Failure Investigation	Product Complaint	Corrective	Product Family	TVT Secur	The polypropylene mesh of the TVT-S product is torn or separated from the Ethisorb fleece pad. See attachment for more details.
	Research and Development	**6**								
					Redacted					
	Sales/Marketing	**1**								
	SQE - External Manufacturing	CAPA080031	Feb 21, 2008	221 days	Implementation	Predictive Indicator	Preventive	Quality Systems	Document Controls	CAPA Initiated to enhance the process of supplier initiated changes as it relates to external manufacturing regardless of the license holder.
		CAPA080070	Apr 27, 2008	154 days	Effectivity	Assembly Error	Corrective	Quality Systems	Device Labeling and Packaging	The European Distribution Center (EDC) overlabeling process is inadequate. For example, Thermachoice was labeled "STOP Not For Human Use"

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Corporate	SQE - External Manufacturing									where it shouldn't.
		CAPA080079	May 5, 2008	147 days	Implementation	Audit Observation	Corrective	Quality Systems	Purchasing Controls	Franchise Procedure for Supplier Quality Management Process, PR-0000286, Revision 1 was not effectively implemented and does not accurately reflect the supplier management process.
		CAPA080080	May 5, 2008	147 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Purchasing Controls	Company Procedure for Supplier Performance measurement, PR120-001, Rev. 18 is not effectively implemented to demonstrate supplier management requirements.
		CAPA080081	May 5, 2008	147 days	Action Plan Approval	Audit Observation	Corrective	Quality Systems	Purchasing Controls	The Company Procedure for Creating Quality Agreements, PR120-009, Rev. 6, has not been effectively implemented, is not aligned with the types & categories of suppliers listed in PR-0000286 & is not maintained consistently.
	SQE - External Manufacturing	**5**								
	SQE - Raw Materials	CAPA060077	Mar 31, 2006	913 days	Failure Investigation	Systemic Issue	Corrective	Quality Systems	Purchasing Controls	Review of Supplier quality process has uncovered possibility of key product components being ordered in ARIBA system without having specifications and or supplier approvals in place
		CAPA060142	Jun 23, 2006	828 days	Implementation	Product Complaint	Corrective	Product Family	Umbilical Tape	Negative trend for cotton (u-tape) breakage in the field. These are all non-confirmed complaints and samples returned for evaluation are within process specification. See attached C-Chart

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Corporate	SQE - Raw Materials									and excel file with complaint numbers and descriptions.
		CAPA080126	Aug 6, 2008	53 days	Implementation	Audit Observation	Corrective	Quality Systems	Purchasing Controls	Gaps exists in supplier certification process as approved in PR550-007, Franchise Supplier Certification Procedure, Version 24.
	SQE - Raw Materials	**3**								
	WW Customer Quality	CAPA080100	Jun 5, 2008	115 days	Implementation	Process Deviation	Corrective	Quality Systems	Complaint Files	Closure Medical has made Ethicon aware of several late complaint notifications. Ethicon as distributor should notify Closure Medical upon complaint initiation, which is not always happening.
		CAPA080109	Jun 13, 2008	108 days	Implementation	Audit Observation	Corrective	Quality Systems	Vigilance Reporting	Vigilance decisions are taken from Ethicon Inc with no evidence of formal approval form Ethicon Sarl even when Ethicon Sarl is the legal manufacturer.
	WW Customer Quality	**2**								
	WW Graphics	CAPA070083	Jun 21, 2007	465 days	Implementation	Systemic Issue	Corrective	Product Process	Products, All: Labeling	North American process for product labeling design and implementation of change has gaps. Frequency and multiple/ overlapping changes has challenged the cross-functional process. Folders, tray lids, foil, boxes, and IFU's can be impacted.

Redacted

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Corporate	WW Graphics									8/2001.
		Redacted								
		CAPA080116	Jun 24, 2008	96 days	Failure Investigation	Finished Goods NC	Corrective	Quality Systems	Device Labeling and Packaging	The incorrect sterility symbology was found on 18 European Valve pack product codes manufactured in San Lorenzo, PR. The sterility methodoloy was labeled as Cobalt irradation however EtO is the sterilization method.
	WW Graphics	**4**								
	WW Risk Management	CAPA080017	Jan 29, 2008	243 days	Action Plan Approval	Predictive Indicator	Preventive	Quality Systems	Vigilance Reporting	Currently there is not integrated process for performing risk management and postmarket surveillance.
		CAPA080090	May 23, 2008	128 days	Failure Investigation	Product Complaint	Corrective	Product Family	Prolene	Investigate suspected Prolene suture breakage in the referenced product complaint.
		CAPA080146	Sep 19, 2008	9 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Risk Management	Product Quality Issue (PQI) process is lacking.
	WW Risk Management	**3**								
Corporate		**47**								
External Manufacturer										
		Redacted								

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
External Manufacturer	External Operations	CAPA070006	Jan 16, 2007	622 days	Implementation	Systemic Issue	Corrective	Quality Systems	Servicing	Not executing according to the servicing section of CFR 820.200 which requires each manufacturer to analyze service reports with appropriate statistical methodology.
	External Operations	**1**								

Redacted

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
External Manufacturer										
					Redacted					
External Manufacturer		**9**								
Internal Manufacturer	Auneau	CAPA060067	Mar 24, 2006	920 days	Implementation	Assembly Error	Corrective	Product Process	Products, All: Finished Product Packaging	Ethicon Auneau has a goal regarding the reduction of mix related nonconformance. Various actions have been identified and are to be performed as continuous improvement around mix related nonconformances. These actions will be documented herein
		CAPA060211	Dec 4, 2006	665 days	Effectivity	Product Complaint	Corrective	Product Family	Ethilon	Important among of complaints recorded for blue ETHILON in Auneau.
		CAPA080003	Jan 9, 2008	264 days	Effectivity	Critical Defect	Corrective	Product Process	Non Product Related: Suture Packaging	Leakage in a pealable sachet on the Multivac 1 equipment
		CAPA080004	Jan 9, 2008	264 days	Implementation	Critical Defect	Corrective	Product Process	Non Product Related: Packing	Mix of IFU in diverse boxes of products during the packing operation. 3 Mixes in BU1 (2 in AL6 / 1 in ASP) 3 mixes in BU2 (1 in ATE / 1 in AMC / 1 in AL5)
		CAPA080011	Jan 23, 2008	250 days	Implementation	Critical Defect	Corrective	Product Process	Non Product Related: Suture Packaging	Leakage in the sachet appeared during the forming of the

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Auneau									cavity on Multivac 1
		Redacted								
		CAPA080026	Feb 8, 2008	234 days	Implementation	Critical Defect	Corrective	Product Process	Non Product Related: Suture Packaging	1 Pack (3 sealed sides pouch) has not been sealed during the operation
		CAPA080027	Feb 8, 2008	234 days	Implementation	Critical Defect	Preventive	Product Process	Non Product Related: Suture Packaging	To secure the sealing processes in order to avoid the non-sealed products on manual sealing processes.
		CAPA080035	Mar 5, 2008	208 days	Failure Investigation	Process Deviation	Corrective	Product Process	E Pack: Assembly	Quality impact on the product due to the lack of identification of one CTQ (knot tensile strenght decrease after EO-sterilization). How to improve the change control process ?
		CAPA080036	Mar 5, 2008	208 days	Implementation	Process Deviation	Corrective	Product Process	E Pack: Assembly	ETHILON porous package and E-Pack compatibility: how to assure the continuity of E-Pack production?
		CAPA080053	Mar 25, 2008	188 days	Failure Investigation	Negative Trend	Corrective	Quality Systems	Quality Records	Negative trend on deviation process regarding documentation and opening of NCR's
		CAPA080054	Mar 25, 2008	188 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Audits	Some suppliers were not listed in the approved suppliers list
		CAPA080055	Mar 25, 2008	188 days	Failure Investigation	Process Deviation	Corrective	Product Process	N-A: Environmental Controls	A deviation has been identified in the management and the control of the parameters of the cleaned areas of production.
		CAPA080056	Mar 25, 2008	188 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Inspection, Measuring, Test Equipment	Some activities of calibration are managed by the technical department (SIP for maintenance and production equipments) but others are also managed by the QA department (equipments in laboratory). The process needs to be harmonized.

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Auneau	CAPA080094	May 29, 2008	123 days	Failure Investigation	Audit Observation	Corrective	Product Process	N-A: Support	Loss of traceability of a product (black nylon of 16cm found in a box of black nylon 30 cm (RM code 819047 and 819049)) in the wharehouse.
		CAPA080095	May 29, 2008	123 days	Failure Investigation	Process Deviation	Corrective	Product Process	Vicryl Rapide: Finished Product Packaging	Deviation regarding the process of air drying for Vicryl rapide: cycles don't finish normally and have to be interrupted by the technical team. The final vacuum values are over 30 µbars.
	Auneau	**16**								
	Cornelia									
					Redacted					
		CAPA070073	Jun 12, 2007	475 days	Implementation	Negative Trend	Preventive	Product Process	PDS: Assembly	PDS size 5/0 Natural suture exhibits a negative trend for Elongation, Knot, In Vitro and In Vivo test results. See attached report for details.
		CAPA070137	Sep 27, 2007	367 days	Implementation	Process Deviation	Corrective	Quality Systems	Production and Process Controls	Based on the HEPA filter certification failure and environmental monitoring action limit excursions, the CME level II area does not meet the requirements established within OP600-107.
		CAPA070138	Sep 27, 2007	367 days	Implementation	Audit Observation	Corrective	Quality Systems	Production and Process Controls	Internal Audit identified failure to meet the requirements of Johnson & Johnson Policy JJP-003 in that requirements for water quality are not defined.
		CAPA070140	Sep 28, 2007	367 days	CAPA Approval	Raw Material NC	Corrective	Quality Systems	Inspection, Measuring, Test Equipment	Increase in number of Prolene knot tensile strength failures reported

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Cornelia									by San Lorenzo from MAS process.
		Redacted								
		CAPA080089	May 22, 2008	129 days	Implementation	Raw Material NC	Corrective	Product Process	Needle Related: Needle Manufacturing	High saturation of hole size variability failures (for Cpk and Standard deviation), large hole failures, and small hole failures in San Lorenzo plant with material originating from Cornelia.
		Redacted								
		CAPA080110	Jun 13, 2008	107 days	Implementation	Process Deviation	Corrective	Product Process	Needle Related: Test-Rel Raw Mat.	Needles final attributes test was entered incorrectly into CIM.
		Redacted								

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Accountability Type	Site of Accountability	CAPA No:	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Cornelia	CAPA080135	Aug 28, 2008	32 days	Failure Investigation	Audit Observation	Preventive	Quality Systems	Process Validation	Validation documentation was unclear regarding rationale for testing not conducted as well as rationale for acceptance of sample results when samples have been lost due to destructive testing errors.
	Cornelia	**14**								
	Gargrave	CAPA070113	Aug 15, 2007	411 days	Effectivity	Systemic Issue	Corrective	Quality Systems	Receiving, Inprocess, Finished Device Acceptance	Receipt sampling process for ASP chemicals does not adequately ensure that all batch numbers received within a delivery are visible to QA.
		CAPA070122	Aug 26, 2007	399 days	Implementation	Finished Goods NC	Corrective	Product Process	Products, All: Support	Differences exist in the Hydroxyproline test method execution between the Skalar and Burkhard test equipment.
		CAPA070144	Oct 2, 2007	363 days	Implementation	Raw Material NC	Corrective	Product Process	Products, All: Labeling	Raw material labelling from suppliers does not always identify JJWM RM code as required by the agreed specification
		CAPA080033	Feb 29, 2008	213 days	Implementation	Systemic Issue	Corrective	Quality Systems	Receiving, Inprocess, Finished Device Acceptance	Traceability of expiry date information for adhesive/lacquer coated packaging webs is not recorded.
		CAPA080065	Apr 14, 2008	168 days	Implementation	Systemic Issue	Corrective	Quality Systems	GLP	Controls around the management of the IR standards library need to be established. Test methods need to be consolidated and linkage within raw material specifications need to be strengthened

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All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Gargrave	CAPA080083	May 12, 2008	140 days	Implementation	Audit Observation	Corrective	Quality Systems	Document Controls	Critical internal audit action raised against the adequacy of storage areas used for archiving of quality records, finished product, raw material & complaint sample retains as required by FDA QSR sec 820.180
		CAPA080085	May 16, 2008	136 days	Implementation	Calibration NC	Corrective	Quality Systems	Inspection, Measuring, Test Equipment	Tighter controls are required around the calibration & use of analytical balances within the QA, Technical & R&D laboratories and those production areas performing analytical measurements.
		Redacted								
		CAPA080120	Jul 14, 2008	77 days	Failure Investigation	Systemic Issue	Corrective	Quality Systems	Document Controls	A discrepancy exists between raw material specification content versus certificate of analysis detail and item master information held in JDEdwards e.g shelf life. CAPA will investigate systems issue that has allowed these discrepancies to occur.

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Gargrave	CAPA080124	Aug 6, 2008	54 days	Implementation	Negative Trend	Corrective	Product Process	Non Product Related: Environmental Controls	Pre facility validation micro monitoring of the CAIS manufacturing area has shown continual environmental air failures. Facility is requried to provide air of sufficient quality for product manufacture.
					Redacted					
	Gargrave	**12**								
	Juarez	CAPA070018	Feb 9, 2007	597 days	Implementation	Process Deviation	Preventive	Quality Systems	Handling, Storage, Distribution	This CAPA is being originated to assess and strengthen the Juarez Supply chain controls and level of compliance to FDA-Customs requirements and Ethicon procedures where required.
		CAPA070129	Sep 5, 2007	390 days	Effectivity	Process Deviation	Corrective	Product Process	Products, All: Environmental Controls	During first quarter of 2007, samples for Bioburden and Dose tests were not collected and sent as required in OP600-005. Audit families with missing samples were JRZ4, JRZ5 and JRZ7 as described in Appendix III of the mentioned Operating Procedure.
		CAPA080009	Jan 17, 2008	255 days	Effectivity	Negative Trend	Preventive	Product Process	Products, All: Assembly	Increasing trend in the complaints from Japan related to incorrect counts on SOT products.
		CAPA080067	Apr 18, 2008	163 days	Effectivity	Process Deviation	Preventive	Product Process	Products, All: Packing	Identify and implement, as applicable, continued improvements in the Juarez split flow process.
					Redacted					

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Juarez									
						Redacted				
	Juarez	**6**								
	Kirkton									
						Redacted				
						Redacted				
		CAPA070172	Nov 28, 2007	306 days	Implementation	Process Deviation	Corrective	Product Process	Products, All: Sterilization-EtO	This CAPA has been raised to facilitate investigation and root cause analysis as a result of a number of Process Deviation NCR's raised for the Vacuum Dwell phase in the Sterilisation Process
						Redacted				

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Kirkton									
					Redacted					
	Kirkton	**9**								
	Neuchatel	CAPA060013	Jan 27, 2006	976 days	Effectivity	Audit Observation	Corrective	Quality Systems	GLP	As part of the Quality training in 2005, it has been identified that some LTR have some mistakes (visa, date missing, calculation wrong ...)
		CAPA060199	Oct 25, 2006	705 days	Effectivity	Raw Material NC	Corrective	Quality Systems	Document Controls	Inserts code "104191" rev.D that should be scrapped in June 2006 due to new revision implementation (rev.E), have been used in October 2006 to produce a batch of 1000 pieces of finish product code 212734.
					Redacted					
		CAPA070092	Jul 5, 2007	452 days	Implementation	Process Deviation	Corrective	Quality Systems	Document Controls	LTR (Lot travel record) must refer good batch No. Two errors detected 1)For

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Accountability Type	Site of Accountability	CAPA No:	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Neuchatel									Prosima PROC2, N° of batch of P18122 (3036253) was referred in place of N° of batch Prosima PROC2 3039404 on LTR. 2)For P18122, Two LTR P18122 refer as same lot No 3037965.
		CAPA070169	Nov 23, 2007	311 days	Implementation	Systemic Issue	Corrective	Quality Systems	Purchasing Controls	Discrepancy of "Certificate of Conformity" contents received from suppliers.
		CAPA080028	Feb 11, 2008	231 days	Implementation	Product Complaint	Preventive	Product Family	TVT O	Preventive CAPA to deploy Component Verification to the EWHU production lines (TVT-O, TVT-STD, Prosima and TVT-S)
		CAPA080105	Jun 13, 2008	108 days	Implementation	Audit Observation	Corrective	Quality Systems	Handling, Storage, Distribution	Procedures do not grant maintenance of microbiological conditions of raw materials and components
		CAPA080108	Jun 13, 2008	108 days	Implementation	Audit Observation	Corrective	Quality Systems	Purchasing Controls	Some Supplier of services are qualified without neither evidence of certification nor audits performed.
		CAPA080123	Jul 31, 2008	60 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	Document Controls	Process release described in procedure EPG07 "Release of finished products" does not cover the inspection of sub-assembly work orders.
		CAPA080129	Aug 26, 2008	34 days	Failure Investigation	Process Deviation	Corrective	Quality Systems	Document Controls	A batch with an NCR and N JDE status can be released in JDE.
	Neuchatel	**12**								
	Norderstedt	CAPA060103	Apr 28, 2006	885 days	Implementation	Critical Defect	Corrective	Product Process	PDS: Sterilization	During visible control by sterilization staff 4 open foiles has been overlooked; CAPA 47/04

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Norderstedt									
						Redacted				
		CAPA060187	Sep 25, 2006	735 days	Implementation	Process Deviation	Corrective	Quality Systems	Production and Process Controls	Process of subject to manufacturing is insecure: without final release by QA Lot XNEH7964G, WO 38545956 was made available stock in the warehouse.
						Redacted				
		CAPA080020	Feb 5, 2008	237 days	Effectivity	Audit Observation	Corrective	Quality Systems	Resources/ Personnel	Ad hoc internal audit 15a/2007 revealed that the rate of missing training documentations is not acceptable
						Redacted				
	Norderstedt	**7**								
	San Angelo	CAPA070036	Apr 2, 2007	546 days	Implementation	Process Deviation	Corrective	Quality Systems	Handling, Storage, Distribution	San Angelo had instances where procedures for handling nonconforming product were not followed. This CAPA will improve specific areas in within the Product Control and Disposition process.
		CAPA070061	May 17,	500 days	Implementation	Product Complaint	Corrective	Quality Systems	Complaint Files	Evaluate complaint sample

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	San Angelo		2007							evaluation process for robustness.
		CAPA070075	Jun 14, 2007	473 days	Implementation	Critical Defect	Corrective	Product Process	Package Related: Sterilization	This CAPA is being originated to address a negative trend that was identified for packets with a wrinkles/pleats defect (critical defect #2006 according to TM403-166). All affected pieces have been detected and captured.
		CAPA070185	Dec 20, 2007	283 days	Effectivity	Critical Defect	Corrective	Product Process	Package Related: Sterilization	This CAPA is being generated to implement a robust method of inspecting sterilization magazine's insert during a purchase from a supplier and in process (manufacturing maintained).
		CAPA080007	Jan 11, 2008	262 days	Effectivity	Process Deviation	Corrective	Product Process	Products, All: Sterilization-EtO	This CAPA is being origianted as a means to document the corrective action of providing an automated pre-run load temperature check for products being processed per PS254-035.
		CAPA080037	Mar 5, 2008	207 days	Implementation	Process Deviation	Corrective	Product Process	Products, All: Distribution	This CAPA is being orignated to address issues raised by a Finish Goods released/hold.
		CAPA080039	Mar 5, 2008	207 days	Implementation	Critical Defect	Corrective	Product Process	Package Related: Packing	An trend of NCRs within the 6UP product family/process for narrow seal was identified. This CAPA is being originated to address 6UP product narrow seal.
						Redacted				
		CAPA080041	Mar 5, 2008	207 days	Implementation	Critical Defect	Corrective	Product Process	Package Related:	Illegible graphics issues have been

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	San Angelo								Labeling	identified in the FIFM Printing Process/ Equipment. This CAPA is being originated to improve and address FIFM illegible graphics printing.
		CAPA080042	Mar 5, 2008	207 days	Implementation	Negative Trend	Corrective	Product Process	Products, All: Packing	A negative NCR (in-process) trend for unaccountable gains in production batches has been identified. This CAPA will provide actions to reduce the incidences of this trend.
		CAPA080049	Mar 15, 2008	198 days	Implementation	Maintenance NC	Corrective	Quality Systems	Servicing	This CAPA is being origianted to document corrective actions for a series of events on Maximo Work Orders completed outside of tolerance dates.
						Redacted				
		CAPA080073	Apr 28, 2008	153 days	Implementation	Critical Defect	Corrective	Product Process	Package Related: Packing	This CAPA will address 2-UP primary open seal critical defect.
		CAPA080074	Apr 28, 2008	153 days	Implementation	Audit Observation	Corrective	Quality Systems	Process Validation	Internal Audit identified a failure, an excel spreadsheet (use to calculate moisture content), to validate computer software for its intended use as required in 21 CFR 820.70.
		CAPA080111	Jun 18, 2008	102 days	Failure Investigation	Process Deviation	Corrective	Product Process	Products, All: Packing	This CAPA is being originated to investigate and implement action(s) for shipping discrepancies, in San Angelo shipping area, to JJHCS.
		CAPA080112	Jun 18, 2008	102 days	Failure Investigation	Critical Defect	Corrective	Product Process	Products, All: Packing	This CAPA is being originated to investigate, implement and document corrective actions for a series (negative trend) of product mixes

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	San Angelo									in the BC area.
		CAPA080115	Jun 23, 2008	97 days	Implementation	Product Complaint	Corrective	Product Family	Needle Related	Complaints for product with PS-5 needles were received from customer reporting an incorrect needle curve. This CAPA will pursue a root cause analysis and establish appropriate corrective actions.
		CAPA080143	Sep 11, 2008	17 days	Failure Investigation	Process Deviation	Corrective	Product Process	Products, All: Test-Rel In Process	Negative trend of incorrect batch ambient exposure tracking process deviations was observed. This CAPA has been originated to ensure proper ambient exposure tracking per OP603-091.
	San Angelo	**18**								
	San Lorenzo	CAPA060018	Feb 2, 2006	969 days	Implementation	Audit Observation	Corrective	Quality Systems	Production and Process Controls	This CAPA conatins the activities related to the implementation of a SL Master Utilities Validation Plan.
		CAPA060020	Feb 2, 2006	969 days	Effectivity	Finished Goods NC	Corrective	Product Family	Prolene	This CAPA is directed at Prolene attachment Finished Good Nonconfromances for swaging techniques failure mode. Management decided to continue further imporvement in the reduction of drilled needles faiulres under this CAPA.
						Redacted				
		CAPA070010	Jan 16, 2007	621 days	Implementation	Assembly Error	Corrective	Product Process	Products, All: Assembly	2006 Assembly Error trending revealed a 3% increase from

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	San Lorenzo									2005 Baseline. Data revealed 3 areas: Mixes, missing Tubing Fluid and Incorrect Count. This CAPA will Address them.
		CAPA070084	Jun 26, 2007	461 days	Effectivity	Critical Defect	Corrective	Product Process	Gynemesh: Finished Product Packaging	This CAPA will address open seal critical defect within the Bar Sealing Process at the Mesh area.
		CAPA070085	Jun 26, 2007	461 days	Implementation	Product Complaint	Corrective	Product Process	Needle Related: Attachment	Product complaint for single arm suture swaged as double arm. Suture strand found with 2 needles instead of one. This CAPA will address this condition.
		CAPA070100	Jul 30, 2007	427 days	Implementation	Audit Observation	Corrective	Quality Systems	ID and Trace	Traceability for zipper tray floor stock item is complex and covers a wide scope. This CAPA is to address this complexity for these floor stock item.
		CAPA070123	Aug 29, 2007	396 days	Implementation	Process Deviation	Corrective	Quality Systems	Production and Process Controls	Incomplete data on the MAS reports. A data communication problem between the MI (Machine Interface) and the PLC have been found resulting in 25 Process Deviatons generated due to incomplete data on the MAS Reports.
		CAPA070152	Oct 19, 2007	345 days	Implementation	Systemic Issue	Preventive	Quality Systems	Document Controls	Preventive CAPA to address to the opportunities found on the assessment performed in OP367-028: "Operating Procedure for the Sampling, Analysis and Disposition of the Incoming Raw Material for Surgical Specialty Products".
		CAPA070159	Nov 9, 2007	324 days	Implementation	Finished Goods NC	Corrective	Product Process	Steel: Finished Product Packaging	A lable discrepancy on 5 units of Surgical Steel, Product Code M657G was

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	San Lorenzo									encountered AT hcs (Memphis Logistic Center) on bathc ZEP750. One label shows code M657G (barcode label), which matches the product, and one shows M65s6G.
		Redacted								
		CAPA080022	Feb 7, 2008	235 days	Implementation	Critical Defect	Corrective	Product Process	Products, All: Packing	Evaluation of packaging critical defects data shows an increase in issues related to the batch print and expiration date. As per management recommendation a CAPA is being requested to address the failure mode in all overwrap-packaging machines.
		CAPA080023	Feb 7, 2008	235 days	Implementation	Critical Defect	Corrective	Product Process	Products, All: Assembly	An NCR increase trend since October 2007 until January 2008 for in process damage suture was identified.
		CAPA080024	Feb 7, 2008	234 days	Failure Investigation	Process Deviation	Corrective	Quality Systems	Nonconforming Product	Batch released without 100% tactile inspection after suture breakage found in previous batch.
		CAPA080025	Feb 7, 2008	234 days	Failure Investigation	Process Deviation	Corrective	Quality Systems	Production and Process Controls	A rewinding process was performed to batch ZKE015. However, there are no documented instructions to capture the rewinding process for Prolene suture size 4/0.
		Redacted								

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	San Lorenzo									of 1.1 as per FM-0000436 V3.
		Redacted								
		CAPA080058	Mar 26, 2008	186 days	Implementation	Assembly Error	Corrective	Product Process	N-A: Assembly	It was reported that there is a little cutting edge on the BV130-5 needle which is supposed to be a taper point needle during his vascular anatomosis procedure. ZAE872 / XAW2808
		Redacted								
		CAPA080068	Apr 22, 2008	160 days	Implementation	Product Complaint	Corrective	Product Process	N-A: Attachment	Confirmed complaints for bent needle condition on ZCP096 & ZJR115, customer reported that the needle was bent at the middle of the body when the package was opened.
		Redacted								

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No:	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	San Lorenzo									ampoulles in the Dry Heat Oven low temperature alarms in Zone 1 were reported by the Yokogawa.

Redacted

CAPA080141	Sep 11, 2008	18 days	Failure Investigation	Audit Observation	Corrective	Quality Systems	CAPA	The corrective and preventive action procedures addressing the investigation of the causes of nonconformities relating to product, processes, and the quality system were not implemented.

Redacted

San Lorenzo	**26**									
Sao Jose dos Campos	CAPA070045	Apr 13, 2007	534 days	Implementation	Critical Defect	Corrective	Product Process	Needle Related: Needle Manufacturing	This CAPA will be analyze the Ophthalmic Needle Process to discover and eliminate root causes, to reduce the loose metal reproved rate.
	CAPA070054	Apr 27, 2007	520 days	Effectivity	Product Complaint	Corrective	Product Process	Products, All: Packing	This CAPA is being opened due to the complaint Increase related to incorrect number of envelopes in the Cecco box.

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Sao Jose dos Campos									
		Redacted								
		CAPA070176	Dec 4, 2007	300 days	Implementation	Raw Material NC	Corrective	Product Family	Gut	This CAPA will be analyzing the Gut tensile strength to address NCR's regarding low resistance for 4-0 diameter. In this scope will be verified other sizes manufactured with 16 mm serosa raw material.
		Redacted								
		CAPA080030	Feb 19, 2008	223 days	Implementation	Negative Trend	Preventive	Product Process	Needle Related: Needle Manufacturing	Negative trend per RAT-0098; A trend of mixed needle was identified in the 100% pre-selection of Needle making process. This CAPA is being originated to investigate this issue.
		Redacted								

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Internal Manufacturer	Sao Jose dos Campos	CAPA080092	May 27, 2008	125 days	Effectivity	Product Complaint	Corrective	Product Family	Ethibond	This CAPA is being opened due to the complaint related to open seal critical defect.
		CAPA080132	Aug 26, 2008	33 days	Failure Investigation	Critical Defect	Corrective	Product Process	Products, All: Needle Manufacturing	This CAPA was opened to investigate the loose metal defect (defect code:1306) in suture finishing area.
	Sao Jose dos Campos	**10**								
	Somerville	CAPA080117	Jun 26, 2008	94 days	Implementation	Raw Material NC	Corrective	Product Family	Wiremill Related	A negative trend has been identified with tensile failures for 2 and 3 mil raw wire used in Micro Needles.
	Somerville	**1**								
Internal Manufacturer		**131**								
Raw Material Supplier										

Redacted

All Active CAPA's

Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description
Raw Material Supplier	Redacted									
	MANGAR INDUSTRIES - NEW BRITAIN, PA (USA)	**2**								
	PERFECSEAL - LONDONDERRY (UNITED KINGDOM)	Redacted								
	PERFECSEAL - LONDONDERRY (UNITED KINGDOM)	**2**								
	Redacted									

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Accountability Type	Site of Accountability	CAPA No.	Date Created	Cycle Time	CAPA State	CAPA Category	CAPA Type	CAPA Scope	Scope Detail	CAPA Description

Redacted